

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/777,526	02/06/2001	Sudhir Agrawal	HYZ-030CPCN3 8659 (47508.518) EXAMINER	
23483	7590 01/05/2004			
HALE AND DORR, LLP 60 STATE STREET			GIBBS, TERRA C	
BOSTON, MA 02109			ART UNIT	PAPER NUMBER
ŕ		·	1635	
		•	DATE MAILED: 01/05/2004	4

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
Advisory Action	09/777,526	AGRAWAL ET AL.					
	Examiner	Art Unit					
	Terra C. Gibbs	1635	· i				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address							
THE REPLY FILED 03 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.							
PERIOD FOR REPLY [check either a) or b)]							
a) The period for reply expires 3 months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.							
2. The proposed amendment(s) will not be entered because:							
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);							
(b) they raise the issue of new matter (see Note below);							
(c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or							
(d) they present additional claims without canceling a corresponding number of finally rejected claims.							
NOTE:							
3. Applicant's reply has overcome the following rejection(s): See Continuation Sheet.							
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).							
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.							
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.							
7.☑ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☑ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.							
The status of the claim(s) is (or will be) as follows:							
Claim(s) allowed:			•				
Claim(s) objected to:							
Claim(s) rejected: <u>1-11 and 15-27</u> .							
Claim(s) withdrawn from consideration:							
8. The drawing correction filed on is a) approved or b) disapproved by the Examiner.							
9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s)							
10. Other:							
·							
	•						

Continuation of 3. Applicant's reply has overcome the following rejection(s): The 35 U.S.C. 112, first paragraph rejection against claims 1-11 for enablement is withdrawn in view of Applicants arguments and Appendix A.

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1-11 and 15-27 would remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,591,721 ('721). Applicants argue that claims 1-11 and 15-27 are not species of the genus of the method of claim 1 of U.S. Patent No. 5,591,721. Applicants argue that the claims of the present invention require at least two different internucleotide linkages as opposed to only one type in the '721 patent. This is not found persuasive because claim 1 of the '721 patent recites "a method for introducing an intact oligonucleotide into a mammal, the method comprising the step of orally administering an oligonucleotide of about 15 to 25 nucleotides, the oligonucleotide comprising phosphorothicate internucleoside linkages between every nucleoside, and further comprising at least two 2'-O-methyl-ribonucleotides at each end". The term "comprising" recited in claim 1 is open language and therefore encompasses an oligonucleotide with phosphorothioate linkages between every nucleoside, in addition to other internucleotide linkages. Therefore, given the "comprising" language, claim 1 of '721 broadly reads on a chimeric oligonucleotide with at least one phosphorothioate linkage and at least one internucleotide linkage selected from the group consisting of alkylphosphonate, phosphorodithioate, alkylphosphonothioate, phosphoramidate, phosphoramidite, phosphate ester, carbamate, carbonate, phosphate triester, acetamidate, and carbozymethyl ester, and further comprising at least one 2'-O-alkyl ribonucleotide, as recited in claim 1-11 and 15-22 of the instant application. Additionally, claim 1 of '721 broadly reads on a chimeric oligonucleotide with at least one phosphorothioate internucleotide linkage, further comprising at least two 2'-O-alkyl ribonucletoides at its 3' and 5' terminal ends, as recited in claims 23-27 of the instant application. Therefore, claims 1-11 and 15-27 are species of the genus of the method of claim 1 of '721. It is noted that the obvious type double patenting rejection against claims 1-11 and 15-27 can be overcome by providing a terminal disclaimer in compliance with 37 CFR 1.321(c), provided the conflicting patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

> KAREN A. LACOURCIERE, PH.D. PRIMARY EXAMINER